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(54) **Surgical tape for treating female urinary incontinence**

Chirurgisches Band zur Behandlung von Harn-Inkontinenz bei Frauen

Bandelette chirurgicale pour le traitement de l'incontinence urinaire féminine

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Description

[0001] The invention relates to a surgical instrument for treating female urinary incontinence, of the type described in WO-A-9003766, comprising a shank having a handle at one end thereof, and a curved needle-like element which is constructed to be connected with the shank to form a curved portion.

[0002] Document WO-A-9606567, which is prior art under Article 54(3) EPC, discloses a surgical incontinence device that allows for alleviating female urinary incontinence while restoring continence by attaching two curved needle to a tape that is intended to be permanently implanted into the tissue between the vaginal wall and the abdominal wall of a patient, thus strengthening the tissue required to restore the urinary incontinence. The surgical instrument according to the present application is an improvement over this instrument, where the tape comprises a netting enclosed by a thin plastic sheath such that insertion is facilitated while avoiding irritation or damage of body tissue.

[0003] The invention will be explained in more detail with reference to the accompanying drawings which disclose the surgical instrument according to the invention and wherein.

FIG. 1 is a side view of the surgical instrument according to the invention,
FIG. 2 is a plan view of the surgical instrument,
FIG. 3 is an exploded side view of one of the needles and tape and shrinkage hose to be connected with said needle,
FIG. 4 is a side view of the needle in FIG. 3 with the tape connected therewith,
FIG. 5 is an enlarged fragmentary axial cross sectional view of a coupling of the instrument for connecting an exchangeable needle thereof, and
FIG 6 is a side view of two needles and a tape interconnecting said needles.

[0004] In the following description the same reference numerals have been used as in WO-A-9606567 for corresponding details of the instrument.

[0005] The surgical instrument comprises a cylindrical tubular shank 10 having at one end thereof a handle 11. At the other end of the shank there is a socket 14. A cylindrical shaft 15 is rotatably mounted in the shank and can be rotated manually by means of a knob 16 mounted to one end of the shaft. The other end of the shaft forms a cylindrical portion 17, FIG 5, of smaller outside diameter than the shaft, which joins a portion 18 having external threads, a smooth end portion 19 of further reduced diameter joining the threaded portion 18, end portion 19 forming a guide pin at said other end of the shaft. Portions 18 and 19 are received in the portion of socket 14 projecting from the shank. The surgical instrument as described so far is in agreement with the instrument disclosed in WO-A-9606567 except that the end portion 14' of socket 14 is flattened from opposite sides (cfr FIGS 1 and 2), so that the cross section of said end portion is non-circular.

[0006] The surgical instrument also includes an exchangeable and disposable needle 21 which at one end thereof is attached to the shank at one end of the needle and extends over substantially a quarter of a circle to the other, free end thereof in order to follow substantially the profile of the pubis between the vagina and the abdominal wall. The needle has uniform circular cross section and has a smooth, preferably polished outside surface. At the free end thereof the needle forms a point 22 by being terminated by a conical portion.

[0007] For attachment of needle 21 to shank 10 the needle forms at said one end thereof a straight portion 30 which is cylindrical but has milled flat faces 31 over that part of said portion 30, extending from the adjacent end of the needle, which shall be received by socket portion 14'. The needle should be oriented in a predetermined rotational position in relation to the shank, and more particularly it should project at right angles to the plane of handle 11. This rotational position is secured by the non-circular shape of socket portion 14' and the end portion of the needle having the flat faces 31, which fits into socket portion 14'. The end portion of the needle having the flat faces 31 joins the body of the needle over e conical portion 32, which tapers towards a shoulder 33.

[0008] An axial blind hole extends from the end surface of the needle said hole having a threaded portion 23 and inwardly thereof a narrower, cylindrical portion 24. Guide pin 19 is dimensioned to be guidingly received by said latter portion when the threaded portion 18 for attaching needle 21 to the rest of the surgical instrument is screwed into threaded portion 23 of the blind hole by rotating shaft 15 by manual rotation of knob 16, the end surfaces of the shank and the needle being pressed against each other. Also this attachment is in agreement with that described in WO-A-9606567.

[0009] When the method as described in WO-A-9606567 is practised two needles 21A and 21B, FIG. 6 of the embodiment described shall be connected one at each end of a tape 26. According to the present invention the tape of the preferred embodiment comprises a mesh or netting forming openings of the order of 1 mm. A suitable material for the tape is PROLENE®, a knitted polypropylene mesh having a thickness of 0,7 mm manufactured by Ethicon, Inc., Sommerville, New Jersey, USA. This material is approved by FDA in USA for implantation into the human body. The netting (tape) preferably has a width of approximately 10 mm and is enclosed in a thin polyethylene sheath 34 which in flattened condition has substantially the same width as the tape although a difference in width is shown in FIG 2 in order to make the provision of the sheath more clear. The length of the netting should be approximately 400 mm. The netting and the sheath are interconnected by means of two rows 35 of stiching. The end portion of the

sheath is attached to the conical portion 32 of the needle by means of a suitable strong glue, and the interconnection of the needle and sheath is covered by a shrink hose 36 of rubber which extends from the shoulder 33 over the conical portion 32 and partly over the cylindrical end portion 30 of the needle. The shrink hose is substantially flush with the surface of the needle at the shoulder. By this arrangement the netting is securely attached to the needle.

[0010] The purpose of sheath 34 is above all to facilitate the insertion of the netting in the manner described in WO-A-06567 i e when the netting is pulled at the ends thereof from the vaginal wall to the abdominal skin and to avoid that rough edges of the netting irritate or damage the body tissues.

[0011] When the tape has been positioned in the correct position as a sling around the urethra the polyethylene sheath shall be removed, and in order to facilitate the removal the sheath should be perforated at the longitudinal center thereof as indicated by a dot-and-dash line 37 in FIG. 6, so that the two halves of the sheath can be withdrawn from the body by pulling at the respective outer ends thereof the halves being separated at the perforation under the influence of the pulling force.

[0012] The purpose of the polyethylene sheath is also to protect the netting during attachment to the needles and during handling before and during insertion into the body.

[0013] The longitudinal center of the tape and sheath should be indicated by a visible colour mark 38, FIG. 6 so that the surgeon readily can see when the netting is symmetrically located with reference to urethra during the surgery.

Claims

1. A tape for treating female urinary incontinence **characterised in that** the tape comprises a netting (26) enclosed by a thin plastics sheath (34).

2. The tape of claim 1 **characterised in that** the netting (26) is made of polypropylene.

3. The tape of claim 1 **characterised in that** the netting (34) is made of polyethylene.

4. The tape of any of claims 1-3 **characterised in that** the sheath (34) is perforated at the longitudinal centre thereof.

5. The tape of any of claims 1-4 **characterised in that** the netting (26) and the sheath are interconnected by stitching (35).

6. The tape of any of claims 1-5 having a first end attachable to a first curved needle-like element (21A) at one end of the first element and a second end of the tape (26) attachable to a second curved needle-like element (21B) at one end of the second element, the elements being intended to be passed into the body via the vaginal wall and being dimensioned to extend from the inside surface of the vaginal wall over the back of the pubic bone to the outside of the abdominal wall.

7. The tape of any of claims 1-6 comprising a first curved needle-like element (21A) attached at one end of the first element to a first end of the tape (26) and a second curved needle-like element (21B) attached at one end of the second element to a second end of the tape (26), the elements being constructed to be connectable independently of each other with the second end of a shank having a handle at a first end of the shank and a second end adapted to receive the first curved needle-like element (21A) or the second curved needle like element (21 B), and the elements being intended to be passed into the body via the vaginal wall and being dimensioned to extend from the inside surface of the vaginal wall over the back of the pubic bone to the outside of the abdominal wall.

8. The tape of claim 7 **characterised in that** the needle-like element comprises a non-circular end portion fitting into a non-circular socket (14') at the second end of the shank (10).

9. The tape of claim 8 **characterised in that** the end portion of the needle-like element (21) joins the rest of the element by a conical portion (32) tapering towards a shoulder (33) on the needle-like element.

10. The tape of claim 9 **characterised in that** the netting (26) and the sheath (34) are connected to the needle-like element (21) by gluing to the conical portion (32).

11. The tape of claim 10 **characterised in that** the netting (26) and the sheath (34) at the site of attachment thereof are covered by a shrink hose (36).

12. The tape of claim 11 **characterised in that** one end of the shrink hose (36) abuts the shoulder (33) and is substantially flush with the surface of the needle-like element at the shoulder.

13. The tape of claim 11 or 12 **characterised in that** the netting (26) and the sheath (34) project from the shrink hose (36) at the other end thereof.

14. The tape of any of claims 1 to 13 **characterised in that** a visible marking (38) is provided on the sheath (34) at the longitudinal centre thereof.

Patentansprüche

1. Band zur Behandlung von Haminkontinenz bei Frauen, **dadurch gekennzeichnet, dass** das Band ein Geflecht (26) aufweist, das von einer dünnen Kunststoffhülle (34) umgeben ist.

2. Band nach Anspruch 1, **dadurch gekennzeichnet, dass** das Geflecht (26) aus Polypropylen hergestellt ist.

3. Band nach Anspruch 1, **dadurch gekennzeichnet, dass** das Geflecht (34) aus Polyethylen hergestellt ist.

4. Band nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, dass** die Hülle (34) in der Mitte der Längsachse perforiert ist.

5. Band nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet, dass** das Geflecht (26) und die Hülle durch eine nicht dem Zusammenziehen dienende Naht (35) verbunden sind.

6. Band nach einem der Ansprüche 1 bis 5 mit einem ersten Ende, das mit einem ersten gebogenen nadelähnlichen Element (21A) an einem Ende des ersten Elementes befestigbar ist, und einem zweiten Ende des Bandes (26), das mit einem zweiten gebogenen nadelähnlichen Element (21 B) befestigbar ist an einem Ende des zweiten Elementes, wobei die Elemente dafür bestimmt sind, in den Körper durch die Scheidenwand eingebracht zu werden, und dimensioniert sind, damit sie sich von der inneren Oberfläche der Scheidenwand über die Rückseite des Schambeins zur Außenseite der Abdominalwand erstrecken.

7. Band nach einem der Ansprüche 1 bis 6, umfassend ein erstes gebogenes nadelähnliches Element (21A), das an einem Ende des ersten Elementes mit einem ersten Ende des Bandes (26) verbunden ist, und ein zweites gebogenes nadelähnliches Element (21B), das an einem Ende des zweiten Elementes mit einem zweiten Ende des Bandes (26) verbunden ist, wobei die Elemente so konstruiert sind, dass sie unabhängig voneinander mit dem zweiten Ende eines Schaftes verbunden sein können, der einen Handgriff an einem ersten Ende des Schafts und ein zweites Ende aufweist, das angepasst ist, um das erste gebogene nadelähnliche Element (21A) oder das zweite gebogene nadelähnliche Element (21B) aufzunehmen, und die Elemente dazu bestimmt sind, in den Körper durch die Scheidenwand eingebracht zu werden, und so dimensioniert sind, dass sie sich von der inneren Oberfläche der Scheidenwand über die Rückseite des Schambeins zur Außenseite der Abdominalwand erstrecken.

8. Band nach Anspruch 7, **dadurch gekennzeichnet, dass** das nadelähnliche Element einen nichtkreisförmigen Endabschnitt aufweist, der in eine nichtkreisförmige Buchse (14') am zweiten Ende des Schaftes (10) passt.

9. Band nach Anspruch 8, **dadurch gekennzeichnet, dass** der Endabschnitt des nadelähnlichen Elementes (21) den Rest des Elementes durch einen konischen Abschnitt (32) verbindet, der sich zu einer Schulter (33) auf dem nadelähnlichen Element verjüngt.

10. Band nach Anspruch 9, **dadurch gekennzeichnet, dass** das Geflecht (26) und die Hülle (34) mit dem nadelähnlichen Element (21) durch Anleimen an dem konischen Abschnitt (32) verbunden sind.

11. Band nach Anspruch 10, **dadurch gekennzeichnet, dass** das Geflecht (26) und die Hülle (34) an ihrem Befestigungsort durch einen Schrumpfschlauch (36) beschichtet sind.

12. Band nach Anspruch 11, **dadurch gekennzeichnet, dass** ein Ende des Schrumpfschlauches (36) an die Schulter (33) stößt und mit der Oberfläche des nadelähnlichen Elementes an der Schulter im Wesentlichen bündig ist.

13. Band nach Anspruch 11 oder 12, **dadurch gekennzeichnet, dass** das Geflecht (26) und die Hülle (34) über den Schrumpfschlauch (36) an dessen anderem Ende vorstehen.

14. Band nach einem der Ansprüche 1 bis 13, **dadurch gekennzeichnet, dass** auf der Hülle (34) eine sichtbare Markierung (38) in der Mitte ihrer Längsachse vorgesehen ist.

Revendications

1. Bandelette pour le traitement de l'incontinence urinaire féminine, **caractérisée en ce que** la bandelette comprend un maillage (26) enfermé dans une fine gaine en plastique (34).

2. Bandelette selon la revendication 1, **caractérisée en ce que** le maillage (26) est fabriqué en polypropylène.

3. Bandelette selon la revendication 1, **caractérisée en ce que** le maillage (26) est fabriqué en polyéthylène.

4. Bandelette selon l'une quelconque des revendica-

tions 1 à 3, **caractérisée en ce que** la gaine (34) est perforée au centre longitudinal de celle-ci.

5. Bandelette selon l'une quelconque des revendications 1 à 4, **caractérisée en ce que** le maillage (26) et la gaine sont reliés par une couture (35).

6. Bandelette selon l'une quelconque des revendications 1 à 5 possédant une première extrémité pouvant être reliée à un premier élément recourbé en forme d'aiguille (21A) à une extrémité du premier élément, et une deuxième extrémité de la bandelette (26) pouvant être reliée à un deuxième élément recourbé en forme d'aiguille (21B) à une extrémité du deuxième élément, les éléments étant destinés à être passés dans le corps via la paroi vaginale et étant dimensionnés pour s'étendre depuis la surface intérieure de la paroi vaginale, à l'arrière de l'os du pubis, jusqu'à l'extérieur de la paroi abdominale.

7. Bandelette selon l'une quelconque des revendications 1 à 6, comprenant un premier élément recourbé en forme d'aiguille (21A) relié à une extrémité du premier élément à une première extrémité de la bandelette (26), et un deuxième élément recourbé en forme d'aiguille (21B) relié à une extrémité du deuxième élément à une deuxième extrémité de la bandelette (26), les éléments étant construits pour pouvoir être reliés indépendamment l'un de l'autre à la deuxième extrémité d'une tige possédant une poignée à une première extrémité de la tige, et à une deuxième extrémité adaptée pour recevoir le premier élément recourbé en forme d'aiguille (21A) ou le deuxième élément recourbé en forme d'aiguille (21B), et les éléments étant destinés à être passés dans le corps via la paroi vaginale et étant dimensionnés pour s'étendre depuis la surface intérieure de la paroi vaginale, à l'arrière de l'os du pubis, jusqu'à l'extérieur de la paroi abdominale.

8. Bandelette selon la revendication 7, **caractérisée en ce que** l'élément en forme d'aiguille comprend une portion d'extrémité non circulaire se plaçant dans un support non circulaire (14') à la deuxième extrémité de la tige (10).

9. Bandelette selon la revendication 8, **caractérisée en ce que** la portion d'extrémité de l'élément en forme d'aiguille (21) rejoint le reste de l'élément par une portion conique (32) s'effilant vers un épaulement (33) de l'élément en forme d'aiguille.

10. Bandelette selon la revendication 9, **caractérisée en ce que** le maillage (26) et la gaine (34) sont reliés à l'élément en forme d'aiguille (21) par un collage au niveau de la portion conique (32).

11. Bandelette selon la revendication 10, **caractérisée en ce que** le maillage (26) et la gaine (34) au niveau du site de fixation de ceux-ci sont recouverts par un élément flexible de rétrécissement (36).

12. Bandelette selon la revendication 11, **caractérisée en ce qu'**une extrémité de l'élément flexible de rétrécissement (36) s'appuie contre l'épaulement (33) et affleure sensiblement la surface de l'élément en forme d'aiguille au niveau de l'épaulement.

13. Bandelette selon la revendication 11 ou 12, **caractérisée en ce que** le maillage (26) et la gaine (34) font saillie depuis l'élément flexible de rétrécissement (36) à l'autre extrémité de celui-ci.

14. Bandelette selon l'une quelconque des revendications 1 à 13, **caractérisée en ce qu'**un marquage visible (38) est prévu sur la gaine (34) au centre longitudinal de celle-ci.

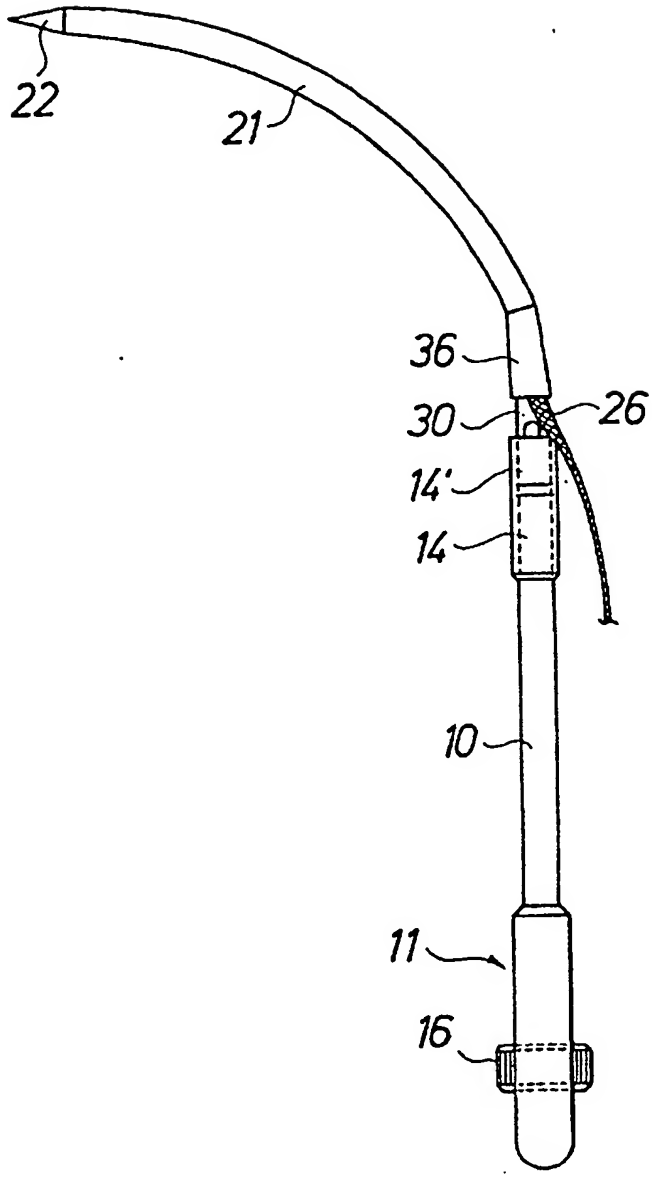

FIG. 1

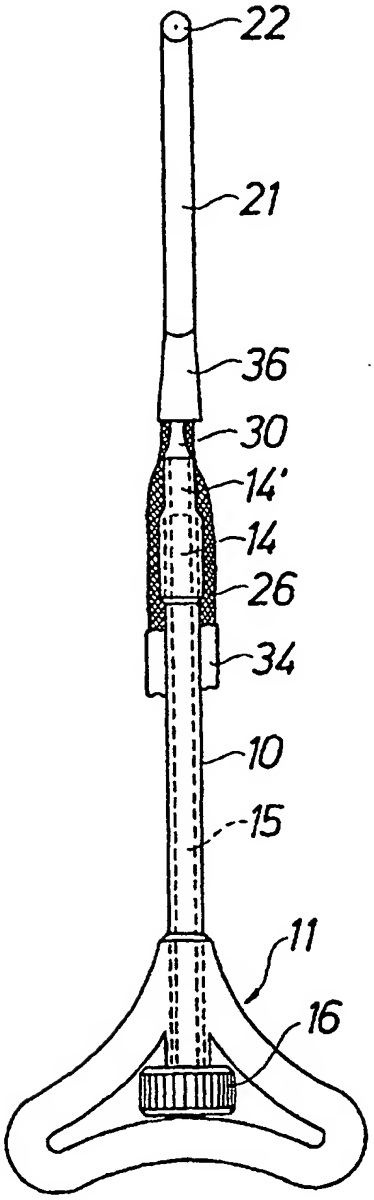

FIG. 2

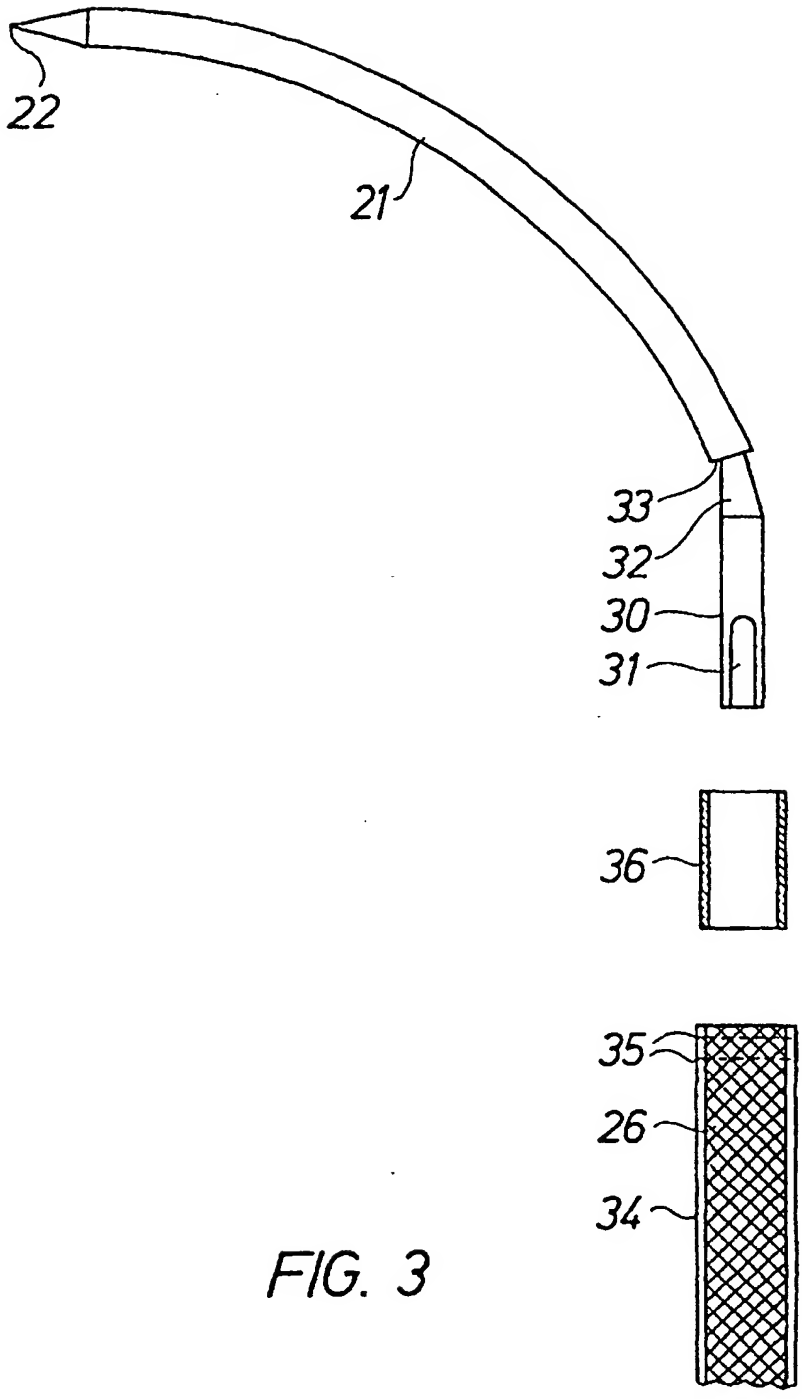

FIG. 3

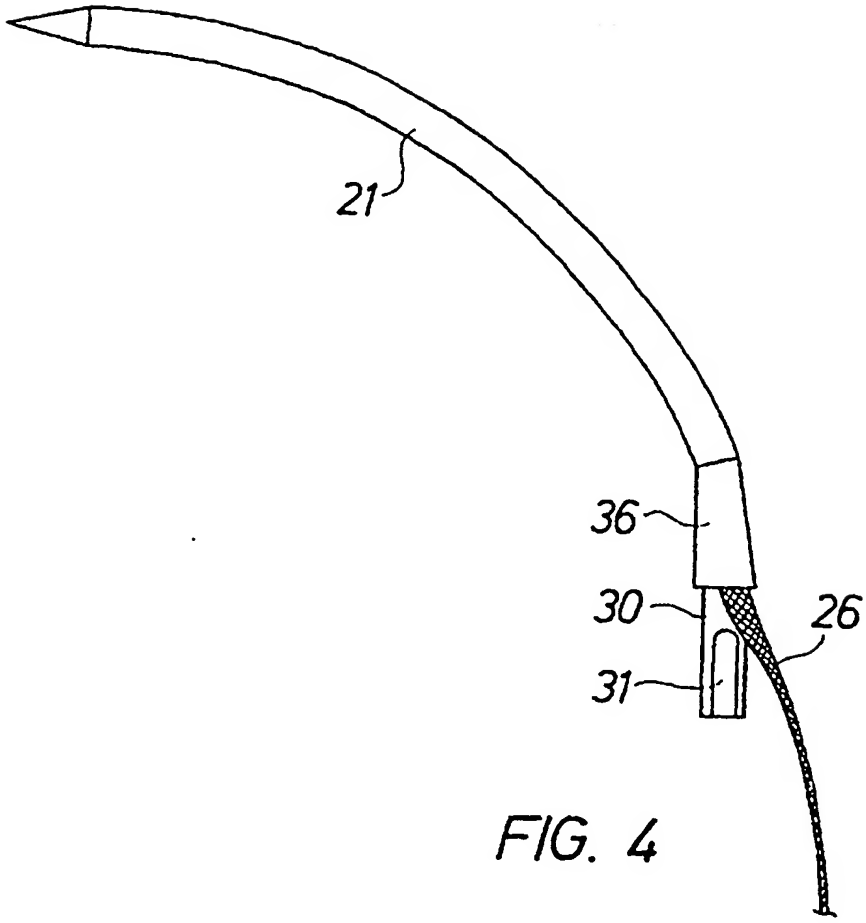

FIG. 4

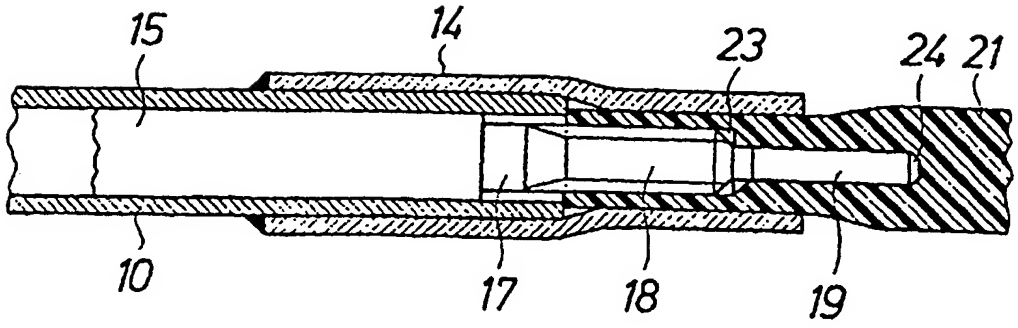

FIG. 5

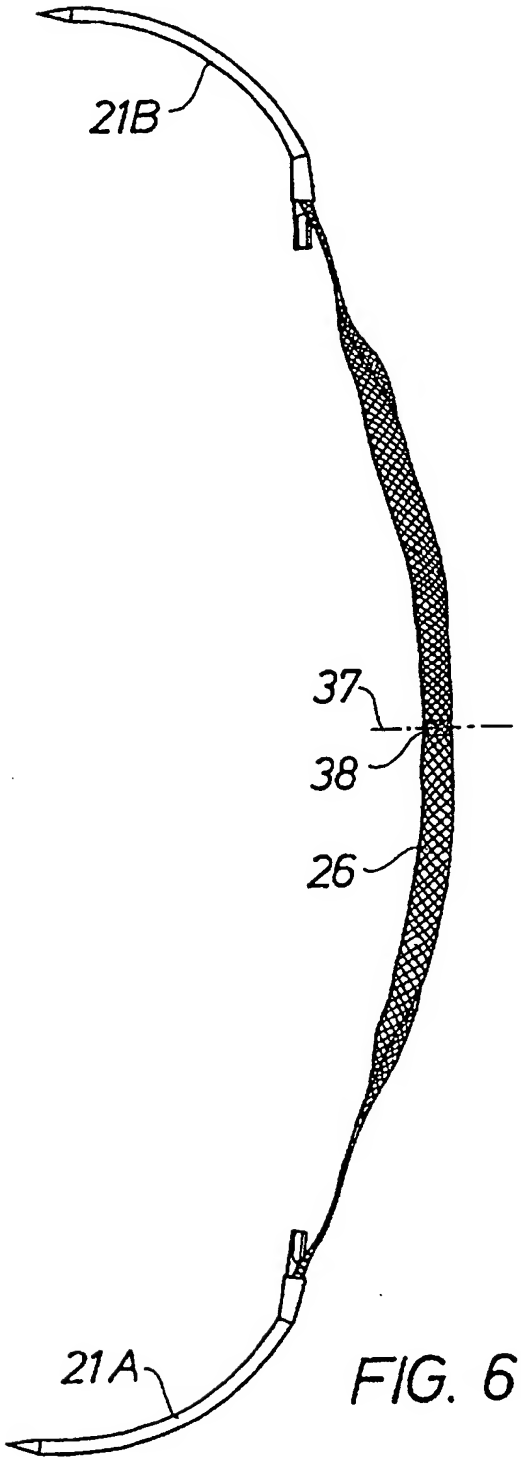

FIG. 6